Medtronic
XOMED

Medtronic Xomed
6743 Southpoint Dr. N.
Jacksonville, Florida 32216-0980

tel 904.296.9600

OCT 1 2 2000

510(k) Summary K002897

1.0 Date Prepared

2.0 Submitter (Contact)

David Timlin
Medtronic Xomed
Jacksonville, FL
(904) 279-7532

3.0 Device Name

Proprietary Name: Titanium Middle Ear Prostheses (Tradename may change)

Common Name(s): Total and partial middle ear prostheses, ossicular replacements

Classification Name: Total and partial ossicular replacements

5.0 Device Classification

Partial Ossicular Replacements	77ETB class II;	21CFR 874.3450	tier 2
Total Ossicular Replacements	77ETA class II;	21CFR 874.3490	tier 2

6.0 Device Description

The Medtronic Xomed (hereafter referred to as Xomed) titanium bucket prosthesis is the standard bucket style commonly found in stainless steel.

The Xomed fixed-length partial and total designs are made entirely of titanium (ASTM F136). The head (round or cam shaped) fits against the tympanic membrane while the shaft extends to the stapes footplate (total) or capitulum (partial).

The Xomed universal titanium prosthesis has two components – a head/shaft and a shoe. The head/shaft component is made entirely of titanium and can be trimmed to the desired length. The shoe has a Flex HA sleeve attached to a titanium bell; the shoe may be modified to create a total or partial prosthesis.

Revised 10/4/00

Current Xomed prosthesis designs for partial and total ossicular reconstruction will be modified with titanium component substitutions.

7.0 Intended Use

Xomed titanium prostheses are intended for surgical implantation into the middle ear as individual replacements for the incus, malleus, or stapes or for the entire ossicular chain, facilitating the mechanical transfer of sound energy from the tympanic membrane to the oval window of the cochlea.

8.0 Substantial Equivalence

The proposed titanium bucket prosthesis is identical to previously cleared titanium bucket prostheses (K883727); no changes are being made in the introduction of this previously cleared device. Other proposed titanium stapes styles are identical to currently marketed Xomed devices.

The proposed titanium total, partial, and universal prostheses are substantially equivalent in size, style, and material to devices currently marketed by Kurz (K990923, K972585, K972492), Stryker Leibinger (K993583), and Micromedics (K992138, K993234).

Conclusion: The titanium MEPs described in this notification have the same intended use as the predicate total and partial ossicular replacements for reconstruction of the ossicular chain, and the same technological characteristics as the predicate ossicular replacements, and so do not raise any new issues of safety of effectiveness.

Tables 1 through 3 contain the comparative design features of the products described.

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Table 1: Comparison of Titanium Bucket Design to Predicate Devices.

	Proposed Titanium Bucket Device	**Treace Medical TYTAN Bucket Prostheses (K883727)**	**Current Medtronic Xomed Bucket Prostheses (Preamendment)**
Intended Use	Partial ossicular chain reconstruction.	Same	Same
Materials	Titanium (ASTM F136)	Titanium (ASTM F136)	Stainless Steel (ASTM F138)
Biocompatible	Yes	Yes	Yes
General description	Bucket design with bail wire	Same	Same

Table 2: Comparison of Proposed Universal and Partial Titanium Designs to Predicate Partial MEPs.

	Proposed Titanium Universal Design (Partial Configuration)	**Proposed Titanium Partial Designs**	**Micromedics/S&T Partial (K993234)**	**Kurz Partial (K990923, K972492)**
Intended Use	Partial ossicular chain reconstruction.	Same.	Same	Same
General description	Two part implant consisting of: • Shaft with head • Shoe	One & two part variations consisting of: • Shaft with head • Shoe	Two part implant consisting of: • Shaft with shoe • Head	One & two part variations consisting of: • Shaft with shoe • Head
Materials	Head/Shaft: Titanium (ASTM F136) with and without H/A coating) Shoe: Titanium (ASTM F136) and Flex H/A	Head/Shaft & Shoe: Titanium (ASTM F136) (with and without H/A coating)	Shaft/Shoe & Head: Titanium (ASTM F67, Grade 4)	Shaft/Shoe & Head: Titanium (ASTM F67)
Biocompatible	Yes	Yes	Yes	Yes
Design Features	• Fenestrated head • Trimmable shaft • Bell shape on end of shaft fits over stapes	• Fenestrated head • Variations with fixed & trimmable shafts • Bell shape on end of shaft fits over stapes	• Fenestrated head • Trimmable shaft • Hollow shoe at end of shaft fits over stapes	• Fenestrated head • Variations with fixed & trimmable shafts • Bell shape on end of shaft fits over stapes
Size	Lengths: 1.75 to 10.5 mm, 0.25 to 0.5 mm increments Shaft Ø: 0.2 – 0.4 mm	Lengths: 1.75 to 10.5 mm, 0.25 to 0.5 mm increments Shaft Ø: 0.2 – 0.4 mm	Lengths: up to 6.5 mm, 0.5 mm increments Shaft Ø: 0.4 mm	Lengths: 1.75 to 4.5 mm, 0.25 mm increments Shaft Ø: 0.2 mm

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Table 3: Comparison of Proposed Universal and Total Titanium Designs to Predicate Total MEPs.

	Proposed Titanium Universal Design (Total Configuration)	**Proposed Titanium Total Design**	**Micromedics/S&T Total (K992138)**	**Kurz Total (K990923, K972585)**	**Stryker Leibinger Total (K993583)**
Intended Use	Total ossicular chain reconstruction.	Same	Same	Same	Same
General description	Two part implant consisting of: • Shaft with head • Shoe	One & two part variations consisting of: • Shaft with head • Shoe	Two part implant consisting of: • Shaft with head • shoe	One & two part variations consisting of: • Shaft with shoe • Head	Two part implant consisting of: • Shaft with offset head • Shoe
Materials	Head/Shaft: Titanium (ASTM F136) with and without H/A coating) Shoe: Flex H/A	Head/Shaft & Shoe: Titanium (ASTM F136) (with and without H/A coating)	Shaft/Shoe & Head: Titanium (ASTM F67, Grade 4)	Shaft/Shoe & Head: Titanium (ASTM F67)	Head/Shaft & Shoe: Titanium (commercially pure, ASTM standard information not available)
Biocompatible	Yes	Yes	Yes	Yes	Yes
Design Features	• Fenestrated head • Trimmable shaft w/ grooves • Shoe is slid over shaft	• Fenestrated head • Variations with fixed & trimmable shafts; shaft is grooved • Shoe is crimped onto shaft for 2-part design	• Fenestrated head • Trimmable shaft w/ grooves • Shoe is crimped onto shaft	• Fenestrated head • Variations with fixed & trimmable shafts, no grooves • Shaft is trimmed beyond the head for two-part design	• Fenestrated head • Trimmable shaft, no grooves • Shoe is crimped onto shaft
Size	Lengths: 1.25 to 10.0 mm, 0.25 to 0.5 mm increments Shaft Ø: 0.2 – 0.6 mm	Lengths: 1.25 to 10.0 mm, 0.25 to 0.5 mm increments Shaft Ø: 0.2 – 0.6 mm	Lengths: 2.0 to 7.5 mm, 0.5 mm increments Shaft Ø: 0.4 mm	Lengths: 3.0 to 7.0 mm, 0.25 mm increments Shaft Ø: 0.2 mm	Lengths: up to 10 mm Shaft Ø: 0.6 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2000

Mr. David Timlin
Director, Regulatory Affairs
Medtronic Xomed, Inc.
6743 Southpoint Dr. North
Jacksonsville, FL 32216

Re: K002897
Trade Name: Titanium Middle Ear Prostheses
Regulatory Class: II
Product Code: 77 ETA, 77ETB
Dated: September 14, 2000
Received: September 18, 2000

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002897

Device Name: _____

Indications for Use:

The proposed universal and bucket-style titanium MEPs are intended for surgical implantation into the middle ear as individual replacements for the incus, malleus, or stapes or for the entire ossicular chain, facilitating the mechanical transfer of sound energy from the tympanic membrane to the cochlea.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

James K. Kane, M.D. 10/04/00

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002897